

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois
corporation,

Plaintiff,

v.

BANNER PHARMACAPS, INC., a Delaware
corporation,

Defendant.

Civil Action No. 07-CV-00754-GMS

REPLY BRIEF IN SUPPORT OF ABBOTT LABORATORIES' MOTION TO DISMISS
BANNER'S FIRST COUNTERCLAIM

September 5, 2008

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I. SUMMARY OF THE ARGUMENT

Abbott has moved to dismiss Banner's first counterclaim, which seeks a declaratory judgment of non-infringement of two now-expired Abbott patents, for lack of subject-matter jurisdiction. Banner responds with a series of non-sequiturs, arguing that because this Court has subject-matter jurisdiction over Banner's **second** counterclaim (an unfair competition counterclaim that is fatally deficient as a matter of law), that jurisdiction must extend to the declaratory judgment counterclaim as well. Not so.

The law clearly instructs that each claim stands on its own and that Article III courts must have subject-matter jurisdiction over a claim throughout all stages of litigation. Here, the Court initially had subject-matter jurisdiction over Banner's non-infringement counterclaim, but that jurisdiction was lost when the patents at issue expired. Because there is no longer subject-matter jurisdiction over Banner's counterclaim seeking a declaratory judgment of non-infringement, this counterclaim must be dismissed under Fed. R. Civ. P. 12(b)(1).

II. LEGAL STANDARD

A motion to dismiss for lack of subject-matter jurisdiction presents a procedural question and does not generally raise issues unique to patent law. *See Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1380-81 (Fed. Cir. 2002) (so holding). Accordingly, the Court must apply regional circuit law, in this case Third Circuit law, in resolving this motion to dismiss. *Id.* This Circuit has made plain that "[t]he requirement that a case or controversy be actual and ongoing extends throughout all stages of federal judicial proceedings, including appellate review." *Rendell v. Rumsfeld*, 484 F.3d 236, 240-41 (3d Cir. 2007). As such, if Banner's first counterclaim now fails to present a justiciable controversy, it **must** be dismissed, regardless of whether, as Banner notes, "there was still jurisdiction when Abbott filed the present action and when Banner counterclaimed." (D.I. 25 at 8); *see Rendell*, 484 F.3d at 240-41.

Additionally – and contrary to what Banner suggests in its response – this motion is not a facial attack on subject-matter jurisdiction. (*See* D.I. 25 at 4.) Abbott has denied the allegations of Banner’s first counterclaim – namely that “[t]here is an actual, substantial, and continuing justiciable controversy between Banner and Abbott regarding infringement of the ‘731 patent and the ‘326 patent” (D.I. 7 ¶ 14) – and has presented outside facts to support its motion.¹ And, where a Rule 12(b)(1) motion presents a factual attack on the jurisdiction of the Court, “no presumption of truthfulness attaches to the allegations of the plaintiff.” *CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008).

III. ARGUMENT

Tellingly, Banner never once claims that this Court presently has subject-matter jurisdiction over Banner’s counterclaim seeking a declaratory judgment of non-infringement. Instead, Banner claims only that there is an actual controversy as to “whether Banner’s product infringed Abbott’s patents when the complaint and counterclaims were filed.” (D.I. 25 at 4.) This statement is both irrelevant and wrong, as will be discussed below.

The central fact is this: subject-matter jurisdiction is a non-negotiable requirement for an Article III court. Here, there is no dispute that Banner’s non-infringement counterclaim no longer represents a live case and controversy because expired patents cannot be infringed; as such, this counterclaim must be dismissed.

¹ In its motion and opening brief, Abbott referred to the patents’ expiry dates, which are not included in Banner’s first counterclaim, as well as other external documents such as press releases and a notice of the status of FDA approval for Banner’s proposed products. (*See* D.I. 23 & Exs. A-C.) Similarly, in Banner’s response, Banner referenced numerous sources external to the pleadings including Banner’s Paragraph IV certification and the text of Banner’s NDA. (*See* D.I. 25 at 2-3.)

A. Because Subject-Matter Jurisdiction Over Banner's First Counterclaim No Longer Exists, The Claim Must Be Dismissed.

Each Article III court has an “independent obligation at the threshold to examine whether [it has] jurisdiction.” *Rendell*, 484 F.3d at 240. But this obligation is not limited to the beginning of a case; just the opposite. As the *Rendell* Court explained, “[t]he central question of all mootness problems is whether changes in circumstances that prevailed at the beginning of the litigation have forestalled any occasion for meaningful relief.” *Id.* (quoting *In re Surrick*, 338 F.3d 224, 230 (3d Cir. 2003)). It simply “does not matter when the case becomes moot.” *Id.* Once that occurs, dismissal for lack of subject-matter jurisdiction is mandatory. *See id.*

Subject-matter jurisdiction requires “a legal controversy that is real and not hypothetical.” *Id.* (internal citations and quotations omitted). Here, because Abbott's two patents have expired, it cannot assert these patents against a potential infringer, and Banner, in turn, cannot seek a declaratory judgment of non-infringement of these patents. *See Pfizer, Inc. v. Ranbaxy Labs, Ltd.*, 525 F. Supp. 2d 680, 685 (D. Del. 2007) (“the existence of issued and *presently enforceable* patent claims against a declaratory judgment plaintiff is a necessary prerequisite to the continued litigation of the declaratory judgment action”). Banner's bid for a judicial declaration of non-infringement, therefore, seeks nothing more than an “impermissible advisory opinion.” *Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 424 (D. Del. 2007) (“To proceed to a substantive ‘court decision’ on the merits of Apotex's claims of noninfringement or invalidity would amount to an impermissible advisory opinion.”) (Sleet, J.), *aff'd* 2008 WL 2753378, at *1 (Fed. Cir. July 16, 2008). On this basis, Banner's first counterclaim must be dismissed.

B. Banner's Two Counterclaims Are Separate and Must Be Treated As Such.

Banner's response attempts to conflate its first counterclaim – which seeks a declaratory judgment of non-infringement of Abbott's patents – with its second counterclaim, which

purports to state a claim for unfair competition based on Abbott's filing of this suit.² This should not divert the Court; the two counterclaims are separate and should be analyzed as such.

First, Banner argues that, in considering Abbott's motion to dismiss the non-infringement counterclaim, "[t]he issue is whether the court has jurisdiction over the counterclaims[]" generally. (D.I. 25 at 8.) This is absolutely wrong. Abbott has not moved to dismiss Banner's unfair competition counterclaim for lack of subject-matter jurisdiction. Abbott instead moved to dismiss that counterclaim months ago for failing to state a claim upon which relief may be granted. The present motion to dismiss on subject-matter jurisdiction grounds is expressly limited to Banner's first counterclaim. (*See* D.I. 22-23.)

Second, Banner, repeatedly insists that "[n]on-infringement is an element of Banner's unfair competition counterclaim[,]" such that the declaratory judgment counterclaim should not be dismissed. (*E.g.*, D.I. 25 at 6.) As an initial matter, this too is false. Non-infringement is not an element of an unfair competition claim. To the contrary, the elements are (1) a "reasonable expectancy of entering a valid business relationship" on plaintiff's part and (2) a defendant who "wrongly interfer[ed]" with that relationship, where (3) such interference "defeat[ed] [plaintiff's] legitimate expectancy and cause[d] [plaintiff] harm." *Total Care Physicians, P.A. v. O'Hara*, 798 A.2d 1043, 1057 (Del. Super. Ct. 2001). Banner cites no authority suggesting that the question of infringement (or non-infringement) is an element of or necessary predicate to a ruling on an unfair competition claim. Indeed, the text of Banner's unfair competition counterclaim

² Banner's response also makes new arguments in support of its unfair competition counterclaim, urging that the filing of this lawsuit prejudiced Banner by causing (i) a two-month delay between the filing of the lawsuit and the expiration of the patents; and (ii) Banner's product to be subject to Abbott's six-month period of regulatory exclusivity. (*See* D.I. 25 at 3 n. 2.) But on October 23, 2007 – a month *before* Abbott filed suit against Banner – Banner's business partner, Noven, stated that "[b]ecause the NDA for Stavzor™ . . . references Abbott Laboratories' Depakote® product, final approval is also subject to the expiration of any applicable exclusivity periods benefiting Depakote®." (D.I. 1, Ex. C.) This same press release made clear that Banner and Noven expected final approval "at the latest, by the end of July 2008[,]" and, accordingly, Noven was preparing for a "2008 launch." (*Id.*) Banner's claims of prejudice are, therefore, entirely baseless.

makes clear that the counterclaim turns on what Abbott knew at the time it filed suit³ – **not** a court’s ultimate decision as to whether Abbott’s patents were infringed. (See D.I. 7 ¶ 17 (“Abbott lacked upon filing their Complaint, and lacks today, a bona fide, objectively reasonable and good faith basis to allege infringement”); see also *id.* ¶ 18 (“Abbott filed this action without substantial justification . . .”).) And, even if infringement were an element of the unfair competition counterclaim, that still would not save the declaratory judgment counterclaim from dismissal. The Court could conduct whatever inquiry is required to resolve the unfair competition counterclaim without keeping a moot declaratory judgment counterclaim alive.

Finally, Banner tries to analogize its unfair competition counterclaim to cases in which the invalidity and enforceability of a patent were considered after the issue of infringement was rendered moot. (See D.I. 25 at 4-6.) But the analogy simply will not hold. Neither *Monsanto* nor *National Semiconductor* – the two cases cited by Banner – deals with a situation like this one.

In *Monsanto*, an alleged infringer filed suit seeking a declaratory judgment that its product did not infringe four patents and that the patents were invalid and unenforceable. See *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1232 (Fed. Cir. 2008). The patentee then counterclaimed asserting the four patents against the alleged infringer. Eventually, the patentee dismissed its claims on three of the four patents and filed a Statement of Non-Liability including a covenant not to sue. *Id.* at 1242. Nevertheless, the *Monsanto* Court determined that

³ At the time Abbott filed suit, it knew that Banner (i) chose Abbott’s Depakote® (divalproex sodium) as the reference-listed drug for Banner’s product (Counterclaim (D.I. 7) ¶ 9); (ii) chose to certify against Abbott’s ‘731 and ‘326 patents, every claim of which specifically relates to divalproex sodium, not valproic acid (see D.I. 25 at 3); and (iii) believed that its product was subject to Abbott’s pediatric exclusivity (see D.I. 1 (Complaint), Ex. C). In its response, Banner now claims – for the first time – that Banner referenced Depakote® because Banner’s product was a “time-release drug” like Depakote®. (D.I. 25 at 2-3.) Under this logic, however, Banner could have chosen any one of a hundred enteric-coated delayed-release tablets with active ingredients entirely dissimilar to that of Banner’s proposed product, all while still relying on those drugs’ safety and efficacy studies simply because they were “time-release drugs.” But Banner specifically chose to reference Abbott’s Depakote® (divalproex sodium) product, and Abbott was not required to credit Banner’s illogical assertion that it filed a Paragraph IV certification as to patents that, according to Banner, had absolutely nothing to do with its proposed product.

it retained subject-matter jurisdiction over the alleged infringer's request for attorney's fees in connection with its counterclaims seeking a judgment that the three patents were invalid and unenforceable. *Id.* The *Monsanto* Court did not, however, allow one substantive claim to provide subject-matter jurisdiction for a separate substantive claim, as Banner seeks to do here.

Similarly, in *National Semiconductor*, the court acknowledged that a patentee's decision to dedicate a patent to the public mooted the issue of non-infringement. *See Nat'l Semiconductor Corp. v. Linear Tech. Corp.*, 703 F. Supp. 845, 850 (N.D. Cal. 1988). The court acknowledged that the question of the validity and enforceability of the patent were relevant to certain antitrust and unfair competition counterclaims, as pled, but explained that this was a case-specific determination because the unfair competition and antitrust counterclaims at issue "turned on a showing of invalidity." *Id.* at 852. The court made perfectly clear, however, that the issue of non-infringement was in no way relevant to an unfair competition counterclaim, saying: "Noninfringement of the '059 patent is no longer relevant to [the] counterclaims. As to that issue, the dedication of the patent leaves no remaining justiciable case or controversy." *Id.* at 850. So, too, here, the expiration of the patents moots the non-infringement inquiry included in Banner's first counterclaim – an inquiry that is wholly unconnected to Banner's unfair competition counterclaim.

What Banner seeks is extraordinary and without precedent. Banner argues that this Court, despite the lack of any live case or controversy regarding infringement, should nevertheless keep a moot counterclaim alive, decide that **same issue** of infringement, and then make a ruling on a separate counterclaim. There is no legal basis for doing as Banner asks; indeed, the command of Article III is that Banner's first counterclaim be dismissed.

C. Banner's Remaining Procedural Arguments Are Not Well-Taken.

Banner's last salvo is to suggest that dismissal of its first counterclaim with prejudice is inappropriate because it could "inadvertently lead to a claim of issue or claim preclusion[]" as to the unfair competition counterclaim. (D.I. 25 at 8.) This is yet another red herring. Unlike the *Bailey* case cited by Banner, this Court is faced with two counterclaims in the same suit filed by the same defendant. There is no risk that this Court will forget Banner's second counterclaim in ruling on Abbott's motion to dismiss Banner's first counterclaim – all of the issues are before the same judge.

Similarly, Banner mistakenly claims that a dismissal with prejudice of its first counterclaim could "preclude Banner from arguing that the lawsuit filed by Abbott was frivolous and an unfounded attempt to keep Banner off the market." (*Id.* at 8-9.) But Banner's unfair competition counterclaim makes that same (meritless) argument in at least two places. (*See* D.I. 7 ¶¶ 17-18.) A dismissal with prejudice of Banner's first counterclaim would have no effect on these arguments.

Finally, Banner seeks leave to amend its second counterclaim to "properly incorporate the facts pled under the first counterclaim." (D.I. 25 at 9.) Respectfully, Abbott suggests that such an amendment would be entirely improper because the merits of an infringement analysis have nothing to do with an unfair competition counterclaim, as Banner's own authority confirms, *see Nat'l Semiconductor*, 703 F. Supp. at 850 (non-infringement was "no longer relevant" to an unfair competition counterclaim), and because no amount of artful pleading can salvage Banner's unfair competition counterclaim as a matter of law. (*See* D.I. 11-12, 17.) In the event that the Court elects to consider Banner's request for leave to amend its second counterclaim, Abbott requests leave to file a brief in opposition.

IV. CONCLUSION

For the reasons set forth above and in Abbott's opening brief, this Court lacks subject-matter jurisdiction over Banner's counterclaim seeking a declaratory judgment of non-infringement and the counterclaim should be dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 12(b)(1).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on September 5, 2008, I caused a true and correct copy of the foregoing document, entitled **Reply Brief in Support of Abbott Laboratories' Motion to Dismiss Banner's First Counterclaim**, to be served on the following persons via the following methods:

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